DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

DEC 11 1998

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Eric E. Tucker, Esq.
Ramsey, Cook, Looper & Kurlander LLC
The IKON Building
Suite 250
101420 Little Patuxent Parkway
Columbia, Maryland 21044

Dear Mr. Tucker:

This is in response to your letter of December 1, 1998 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)) on behalf of the Sumer Distributing Company, Houston, Texas. Your submission states that Sumer Distributing Company is marketing a product that it asserts is a dietary supplement and that bears the claim "...it is taken under the tongue for 3 minutes before swallowing. It has been proven that by taking nutrients under your tongue the absorption into your circulatory system is 90 - 95% vs. only 5 - 10% when swallowed."

This statement in the labeling indicates that your product is intended for use as a sublingual, which would mean that it would not meet the statutory definition of a dietary supplement contained in 21 U.S.C. 321(ff), and therefore, could not be marketed as a dietary supplement.

The term "dietary supplement" is defined in 21 U.S.C. 321(ff). 21 U.S.C. 321(ff) provides that the term means a product (other than tobacco) intended to supplement the diet that bears or contains a vitamin, a mineral, an herb or other botanical, an amino acid, a dietary substance for use by man to supplement the diet by increasing the total dietary intake, or a concentrate, metabolite, constituent, extract, or combination of any of the above ingredients. 21 U.S.C. 321(ff) further states that dietary supplements are intended for ingestion in a form described in 21 U.S.C. 350(c)(1)(B)(i) or in compliance with 21 U.S.C. 350(c)(1)(B)(ii), are not represented as conventional food or as a sole item of a meal or the dietary, and are labeled as a dietary supplement.

The quoted labeling statement indicates that **Renaissance Sun Powered Energy Blend** is not a product "intended for ingestion." As stated above, the definition of dietary supplement in 21 U.S.C. 321(ff) states that a dietary supplement is a product "intended for ingestion." The term "ingestion" has been addressed by the court in United States v. Ten Cartons, Ener-B Nasal Gel, 888 F. Supp. 381, 393-94 (E.D.N.Y.), aff'd, 72 F.3d 285 (2d Cir. 1995), which states:

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> The ordinary and plain meaning of the term "ingestion" means to take into the stomach and gastrointestinal tract by means of enteral administration. See Stedman's Medical Dictionary (4th Lawyer's Ed. 1976) (defining ingestion as the "introduction of food and drink into the stomach."); Webster's Third New International Dictionary (1976) (defining ingestion as "the taking of material (as food) into the digestive system.")...
>
> The interpretation of the term "ingestion" to mean enteral administration into the stomach and gastrointestinal tract is also supported by the language of the statutory sections immediately preceding and following section 350(c)(1)(B)(ii). Section 350(c)(1)(B)(i) states that the vitamin must be intended for ingestion in tablet, capsule or liquid form. Each of these forms denotes a method of ingestion that involves swallowing into the stomach. Section 350(c)(2) states that a food is intended for ingestion in liquid form under section 350(c)(1)(B)(i) "only if it is formulated in a fluid carrier and is intended for ingestion in daily quantities measured in drops or similar small units of measure." This elaboration of "liquid form" also denotes ingestion by swallowing the fluid.

Therefore, because the term "ingestion" means introduced into the gastrointestinal tract, a product introduced into the mouth and from which the ingredients are absorbed trans-mucosally prior to ingestion is not subject to regulation as a dietary supplement because it is not "intended for ingestion." Moreover, the product's labeling contains claims for the product for example, that it is intended for "supporting the immune system", that are subject to 21 U.S.C. 321(g)(1)(C), and that may subject the product to regulation under the drug provisions of the Act.

Please contact us if you require further assistance.

Sincerely,

Lynn A. Larsen, Ph.D.
Director
Division of Programs and Enforcement Policy
Office of Special Nutritionals
Center for Food Safety
and Applied Nutrition

Copy:
Mr. Jonathan Katzen
President
Sumer Distributing Company
10801 Hammerly Blvd., Suite 150
Houston, Texas 77043

Copies:
FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200
FDA, Baltimore District Office, Office of Compliance, HFR-MA240

cc:
HFA-224 (w/incoming)
HFA-305 (docket 97S-0163)
HFS-22 (CCO)
HFS-456 (file)
HFS-450 (r/f, file)
HFD-310 (BWilliams)
HFD-314 (Aronson)
HFS-600 (Reynolds)
HFS-605 (Bowers)
GCF-1 (Dorsey, Nickerson)
r/d:HFS-456:RMoore:12/8/98
Init:GCF-1:DDorsey:12/10/98
f/t:HFS-456:rjm:12/10/98:docname:62612.adv:disc34

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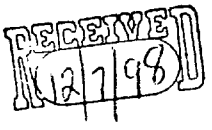
Reply To: Eric E. Tucker, Esq.

December 1, 1998

Via U.S. Mail



Elizabeth A. Yetley, Director
Office of Special Nutritional, HFS-450
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street, S.W.
Washington, DC 20204

Dear Ms. Yetley:

Pursuant to 21 C.F.R. § 101.93(c), our client, Sumer Distributing Company, is hereby notifying the Food and Drug Administration that within the last thirty (30) days it has commenced marketing its Sumersun Renaissance Nutritional Supplement with the following structure/function claims on the Product's Label:

"Live Life with Energy"

and

"Liquid Solar Energy. Renaissance ™ rejuvenates your body at the cellular level while increasing energy and stamina - complements of sunshine and biophysics. Our unique solar distillation process uses the power of sunlight to transform the simple ingredients into a nutrient rich energy blend. The benefits of concentrated plant originated proteins and nucleotides maximize the antioxidant capabilities of Renaissance ™."

These claims are immediately followed by the required disclaimer language in bold type.

Sumer Distributing Company is also utilizing a brochure which will be distributed at the point of sale of the Renaissance ™ product. A copy of the text of said brochure is attached hereto, and the statements in said brochure are also being submitted pursuant to 21 C.F.R. §101.93.

Please let us know if there is any additional information required regarding this submission.

Very truly yours,

Eric E. Tucker

Enclosure

CERTIFICATION

Sumer Distributing Company hereby certifies that the information contained in this Notice is a complete and accurate description of the structure/function claims made on the labeling of the Renaissance ™ product label. Sumer Distributing Company further certifies that is has substantiation that the statements on the product label and in the product brochure submitted herein are truthful and not misleading.

By:_____
Jonathan Katzen, President

Nourish your body...
From the very source of life itself!

The Story of SumerSun™ Renaissance™ Sun-Powered Energy Blend

An advanced formulation which rejuvenates your body at the cellular level while increasing energy and stamina...Complements of sunshine and biophysics.

1st page

The scientific theory of Sun Power and its effect on energy

The beneficial effects of Renaissance™ result from a combination of forces. The effects of our **solar distillation/extraction process photoactivate the 100% natural ingredients.** These reactions are stimulated by the absorption of sunlight in a controlled environment. The antioxidant qualities of the organically grown fruit juices and teas provide nutritional support for the normal functioning of the immune and circulatory systems. A theory now under study suggests that concentrated energy from sunlight nourish our cells and genes in such a way that permit our bodies to take advantage of this free energy. All cells are nourished through the action of the Krebs Cycle. Renaissance™ contains specific amounts of phosphates and nucleotides, the basic components of our cells as well as ATP which provides support for an efficient Krebs Cycle. Nucleotides ensure that our genes remain healthy and can influence protein conversion to enhance energy and vitality. Cells that are provided with energy age slower and return the self-healing powers of the body to full force. For more information on SumerSun™ Renaissance™ Sun-Powered Energy Blend, visit our Web site at www.sumersun.com.

4th page

SUMERSUN

POWERED BY SUNLIGHT

Sumer Distributing Company
10801 Hammerly Blvd., Suite 150
Houston, TX 77043
888-893-3383
http://www.sumersun.com

These statements have not been evaluated by the Food and Drug Administration. This Product is not intended to diagnose, cure or prevent any disease.

Renaissance™ — a gift from nature ... and microbiology

Two thousand years before written history began, a civilization known as the Sumerians learned how to harness the power of the sun. With this knowledge they transformed a land of dust and mud into a great civilization whose honored and ancient knowledge became the foundation for the great cultures of Egypt, Greece, Rome — indeed, the western world. Like the Sumerians we have found the secret of harnessing the sun's energy.

Sunlight and plants

Plants are acknowledged to be a superior source of antioxidants and are considered by some as the ultimate solar battery. Renaissance™ transforms certified concentrated organic fruit juices, grade A Canadian honey and imported herbal and oolong teas into an extraordinary powerhouse of micronutrients using our unique solar distillation process. Like plants, our photoactivation process changes solar power into chemical energy, which provide readily available support for healthy cells. When cells are properly nourished they may have the ability to slow the aging process as well as increasing genetic efficiency.

Medical scientists impressed with results

Developed in the deserts of west Texas by an eminent bio-physicist, and sold in Europe since 1992, Renaissance™ has been the focus of clinical trials and medical research studies. SumerSun™ Renaissance™ has been accepted among people conscious of the benefits of nature's products in maintaining good health. Physicians have credited Renaissance™ for enhancing energy and vitality as well as supporting the immune system. Renaissance™ has made such an impact in Europe that it has received the coveted German government's Seal of Recommendation. Renaissance™ contains no artificial flavors, colors, sulfates or preservatives and is caffeine and microbe free. Renaissance™ is 100% satisfaction guaranteed.

2nd page

Renaissance™ Sun-Powered Energy Blend...nutrients so concentrated you need only a few drops.

Did you know that most bottled fruit juices are only about 5% solids and the rest is filtered water? Renaissance™ has over 45% solids! We drink fruit juice because we want the micronutrients, which are provided from the fruit solids. It is these solids that contain the micronutrients that rejuvenate and nourish our cells. To maximize the benefits of Renaissance™ it is taken under the tongue for 3 minutes before swallowing. It has been proven that by taking nutrients under your tongue the absorption into your circulatory system is 90 - 95% vs. only 5 - 10% when swallowed.

Energy to run, energy to rest

Renaissance™ is quite the opposite of sugar-based energy drinks, which provide an easy-come/easy-go energy jolt. In fact, SumerSun™ Renaissance™ provides long lasting, consistent energy... And then some. Remember our photoactivation process we spoke about earlier? By nourishing your body's cells with readily available energy, cell communication may be increased. This revitalization begins immediately and many people notice a better quality of sleep, a possible indication you are receiving sufficient cellular energy. However, the real benefits of Renaissance™ are incremental. Experience suggests that by making Renaissance™ a part of your daily routine for three weeks you will begin to unlock your body's incredible energy potential.

SumerSun

Renaissance

Sun Powered energy Blend

will renew your sense of well-being.

And we'll reward you with a $2 or $4 REBATE on your first bottle.

3rd page